DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

#14

Re: CELLCEPT®
Docket No. 95E-0300

NOV 30 1995

The Honorable Bruce Lehman
Assistant Secretary of Commerce and
Commissioner of Patents and Trademarks
Washington, D.C. 20231

Dear Commissioner Lehman:

This is in regard to the application for patent term extension for U.S. Patent No. 4,753,935, filed by Syntex Inc., under 35 U.S.C. § 156 et seq. We have reviewed the dates contained in the application and have determined the regulatory review period for CELLCEPT®, the human drug product claimed by the patent.

The total length of the regulatory review period for CELLCEPT® is 2,479 days. Of this time, 2,304 days occurred during the testing phase and 175 days occurred during the approval phase. These periods of time were derived from the following dates:

1. The date an exemption under subsection 505(i) of the Federal Food, Drug, and Cosmetic Act involving this drug product became effective: July 21, 1988.

   The applicant claims June 24, 1988, as the date the Investigational New Drug application (IND) became effective. However, FDA records indicate that the IND effective date was July 21, 1988, which was thirty days after FDA receipt of IND 31,747 on June 21, 1988.

2. The date the application was initially submitted with respect to the human drug product under subsection 507 of the Federal Food, Drug, and Cosmetic Act: November 10, 1994.

   FDA has verified the applicant's claim that the New Drug Application (NDA) for CELLCEPT® (50-722) was initially submitted on November 10, 1994.

3. The date the application was approved: May 3, 1995.

   FDA has verified the applicant's claim that NDA 50-722 was approved on May 3, 1995.

This determination of the regulatory review period by FDA does not take into account the effective date of the patent, nor does it exclude one-half of the testing phase as required by 35 U.S.C. § 156(c)(2).

Please let me know if we can be of further assistance.

Sincerely yours,

Stuart L. Nightingale, M.D.
Associate Commissioner
for Health Affairs

cc: Pauline Ann Clarke
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